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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/529,524

08/19/2005

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701586-052823-US

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09/22/2008

EXAMINER

JEAN-LOUIS, SAMIRA JM

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/529,524	<b>Applicant(s)</b> RAVID ET AL.	
	<b>Examiner</b> SAMIRA JEAN-LOUIS	<b>Art Unit</b> 1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26,33 and 37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-26,33 and 37 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

**DETAILED ACTION**

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Group I, claims 1-13 are drawn to a method for downregulating estrogen receptors in a population cells expressing an estrogen receptor comprising delivering to said population of cells an effective amount of at least one adenosine analog and a pharmaceutically acceptable carrier to down-regulate estrogen receptor levels.

II. Group II, claims 14-17 are drawn to a method of suppressing cell cycle and/or cellular growth in a population of cells comprising delivering to the cell population an effective amount to downregulate estrogen receptor levels, at least one adenosine analog and a pharmaceutically acceptable carrier.

III. Group III, claims 18-24 are drawn to a method of treating an individual affected with malignant cell growth in a tissue or plurality of tissues expressing estrogen receptors, the method comprising administering to the individual a sufficient amount of an adenosine agonist to downregulate estrogen receptors in a cell population in the tissue or plurality of tissues and a pharmaceutically acceptable carrier.

IV. Group IV, claims 25-26 drawn to a method of identifying a compound suitable for treating malignant cell growth in a tissue which expresses estrogen receptors, the method comprising measuring the amount of estrogen receptor expression in a cell, administering an adenosine analog to the cell, and measuring the expression of estrogen receptor after administration of the adenosine analogue, wherein reduction in the amount of estrogen receptor in the cell after administration of the adenosine analogue indicates identification of a compound suitable for treating malignant cell growth.

V. Group V, claim 33 is drawn to a kit for downregulating estrogen receptors in a population of breast and/or ovarian cancer cells comprising in a container at least one adenosine analog capable of downregulating estrogen receptors, wherein the adenosine analog is an adenosine A3 receptor agonist selected from the group consisting of N6-(3-iodobenzyl)adenosine-5'-N-methyluronamide, 2-chloro-adenosine, in the population of cells in a pharmaceutically acceptable carrier in a vial or tube, a means for detecting downregulation of estrogen receptors in the population cells, and an instruction manual exemplifying how to measure estrogen receptor downregulation using the means provided in the kit.

VI. Group VI, claim 37 is drawn to a kit for detecting compounds capable of downregulating estrogen receptors in a population of cells comprising: a population of test cells expressing estrogen receptors in a suitable cell growth medium or freezing medium or storage medium;

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A standard adenosine analog of capable of downregulating estrogen receptors in the population of test cells as powder or in a suitable buffer with known concentration;

A means for detecting estrogen downregulation in the test cell population, wherein the test cell population comprises malignant cells, wherein the malignant cells are breast and/or ovarian cancer cells and wherein the malignant cells are resistant to various compounds disclosed in the claim; and an instruction manual outlining exemplary cell growth conditions to detect downregulation of estrogen receptors in the test cell population using the standard adenosine analog, wherein the standard adenosine analog is selected from the group consisting of adenosine A3 receptor agonist N6-(3-iodobenzyl)adenosine-5'-N-methyluronamide and 2-chloro-adenosine.

The inventions listed as Groups I, II, III, IV, V, and VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept (PCT Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features.

The expression “special technical features” is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings. Whether or not any specific technical feature makes a “contribution” over the prior art, and therefore constitutes a “special technical feature”, should be considered with respect to novelty and inventive step.

In this instant application, the common technical feature in all groups is the adenosine analog. This compound cannot be said to be a special technical feature under PCT Rule 13.2 because adenosine analog is shown in the prior art.

In this case, Pohlke et al. (US Patent 3,838,147) teaches Adenosine derivatives (i.e. adenosine analog) useful for increasing coronary blood flow and improving circulation (see abstract). As a result, no special technical features exist among the different groups because the inventions in Groups I, II, III, IV, V, and VI fail to make a contribution over the prior art with respect to novelty and inventive step. In conclusion, there is a lack of unity of inventions, and therefore restriction for examination purposes as indicated is proper.

### ***Species Election***

This application contains claims directed to more than one species of the generic invention. These species either possess divergent structures and/or physical properties

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(N6-(3-iodobenzyl)adenosine-5'-N-methyluronamide vs. 2-chloro-adenosine. Thus, these species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species listed below do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same special technical feature among the different species.

The following claims 1-26, 33, and 37 are generic.

**The species are as follows:**

Applicant is required to elect a particular adenosine analog to be used in the aforementioned inventions. Alternatively, applicant may elect a particular adenosine analog listed in claims 6, 7, or 33.

Applicant is required to elect a particular cell type to be used in the method of groups III-VI. Alternatively, applicant may elect a particular type of cell listed in claims 19, 20, 24, or 26.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

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are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

No telephone call was made due to the complexity of the election/restriction.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-5 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1617

09/17/08

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617